Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0950316	07/05/2018
Name of Provider or Supplier	**Street Address, City, State**	
Pediatrics East, Inc-Bartlett	8025 Stage Hills Blvd, Bartlett, TN	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of the laboratory's performance evaluation report obtained from the laboratory's proficiency testing provider, the laboratory's proficiency testing records, email communication with the laboratory's proficiency testing provider and interview with the laboratory coordinator, the laboratory failed to take remedial action for the red blood cell (RBC) analyte for proficiency testing 2018 event one. The findings include: 1. Review of the laboratory's performance evaluation report obtained from the laboratory's proficiency testing provider revealed the following samples scored as unacceptable for the RBC analyte HD-1, HD-2, HD-3, HD-4 resulting in an overall score of 20% for the RBC analyte. 2. Review of the laboratory's proficiency testing records revealed no remedial action had been taken for the unsatisfactory RBC analyte for 2018 event one. 3. Email communication with the laboratory's proficiency testing provider revealed that the performance evaluation reports for 2018 event 1 were available on April 20, 2018. 4. Interview with the laboratory coordinator on July 5, 2018 at 2:30 pm confirmed the laboratory had not printed their performance evaluation reports since the April 20, 2018 release and had not taken remedial action for the unsatisfactory performance for the RBC analyte for 2018 event one.
D5400	ANALYTIC SYSTEMS

	CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: The laboratory failed to follow manufacturer's instructions for calibration for the complete blood count (CBC) instrument (Refer to D5437); and failed to document all CBC quality control procedures performed (Refer to D5441).
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review the CellDyn Emerald complete blood count (CBC) manufacturer's instructions for calibration, the laboratory's Celldyn Emerald CBC instrument calibration records, the laboratory's quality assurance plan and interview with the laboratory coordinator, the laboratory failed to follow manufacturer's instructions for calibration of the CellDyn Emerald CBC instrument in 2016, 2017, and 2018 for four of five calibrations performed. The findings include: 1. Review of the CellDyn Emerald CBC manufacturer's instructions for instrument calibration for the CellDyn Emerald CBC instrument revealed the following: "Using the Calibration Verification Worksheet from Appendix E, enter the assay value into the first column and the mean from the result file into the second column. If the difference between the two columns exceeds the +/- limit shown on the Calibrator Assay Sheet, calibration is required." "Make a copy of the completed calibration worksheet and save for your records." "Calibration Verification is done to verify the accuracy of the calibration. It is accomplished by running the second tube of calibrator in the same manner as the first and comparing the results to the Assay Values." 2. Review of the CellDyn Emerald CBC instrument calibration records revealed the following: December 30, 2016 calibration: no use of calibration verification worksheet, no comparison with assay sheet, calibration target range for MCV of 86 to 90, post calibration value = 84.9. June 14, 2017 calibration: no use of calibration verification worksheet, no post calibration verification with comparison to the assay sheet. January 24, 2018 calibration: no use of calibration verification worksheet, no documented comparison with assay sheet, calibration target range for red blood cell of 4.04 to 4.24, post calibration verification

	value = 3.94; calibration target range for hemoglobin of 10.9 to 11.3, post calibration verification value = 11.4. June 26, 2018 calibration: no use of calibration verification worksheet, no post calibration verification with comparison to the assay values. 3. Review of the laboratory's quality assurance plan revealed that calibration is reviewed for timeliness only. 4. Interview with the laboratory coordinator on July 5, 2018 at 2: 30 pm confirmed that the laboratory failed to follow manufacturer's instructions for use of the calibration verification worksheet, comparison with the assay sheet for target range acceptablility, and post calibration verification when performing calibration of the CBC instrument in 2016, 2017, and 2018. The calibrations are not reviewed for completeness and accuracy.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation of the laboratory and interview with the laboratory coordinator the laboratory failed to document all quality control (QC) procedures performed in 2016, 2017, and 2018. The findings include: 1. Observation of the laboratory on July 5, 2018 at 9:00 am revealed the Celldyn Emerald complete blood count (CBC) instrument in use for patient testing. 2. Review of the 2016, 2017, and 2018 CBC QC records revealed no documentation of repeated QC with the performance of daily QC. 3. Interview with the laboratory coordinator on July 6, 2018 at 1:30 pm revealed the following: The laboratory retains daily quality control printouts until the monthly quality control reports are printed. Prior to printing the monthly quality control reports the lead testing personnel deletes any quality control runs that are not within range from the quality control files. The daily control printouts are then discarded. The laboratory coordinator confirmed that the laboratory failed to detect errors when CBC QC was performed until acceptable limits were met and failed to document all control procedures performed in 2016, 2017, and 2018.